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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,165	06/24/2002	Seizo Sunago	221181US3PCT	9703
22850	7590	03/07/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/089,165	SUNAGO ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 November 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 March 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-9, 11-15 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,019,752 to Sunago et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Sunago patent discloses the infusion container with dissolving solution chamber and medication chamber

arranged as claimed, as well as the communication hole, protruding support piece, and movement of the claimed structure to permit fluid communication.

The claims are not identical in language, preventing a statutory double-patenting rejection. One of ordinary skill in the art would know that a drug storing chamber is equivalent to the instantly claimed medicine storing chamber (see definition of "drug" as a substance used for medication, Merriam-Webster's Collegiate Dictionary, 10th Ed., 2001), and that the solvent chamber is equivalent to the instantly claimed dissolving liquid storing chamber (see definition of "solvent" as a liquid substance capable of dissolving one or more other substances, Merriam-Webster's Collegiate Dictionary, 10th Ed., 2001).

Furthermore, claim 5 of the '752 Sunago patent comprises within a chamber "a chamber within which is storable a drug...agent....". Claim 5 does not specify which outer chamber comprises this inner chamber. But since claim 5 depends from claim 4, which depends from claim 1, it is possible that the inner chamber is contained within the drug storing chamber. The Sungao patent further claims the rotational motion of the capping member to create fluid communication between the chambers.

Therefore, though the claim language is not identical, the pending claims are unpatentable over the patented case.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,352,196 to Haber et al.

In the specification and figures, Haber discloses the invention substantially as claimed by applicant. In particular, Haber discloses a plastic mixing vial with a large outer chamber 204, a cup-shaped receptacle 226 that contains a medicine, and a further inner cylinder 208 that contains a medicine. The inner cylinder has a bottom sealing element 212 with grooves that engage the inner surface of receptacle 226 to create a friction fit in the inactivated condition. The inner cylinder 208 has an open mouth in the absence of the piston 228. Applicant's "open mouth" assembly contains piston 20, indicating that an open-mouth container as claimed by applicant may incorporate a piston and a cap. The device further comprises a protruding fitting member 216 and holes or trenches 262 in the bottom of inner container 208, a claw-like cap 266 with a ring protruding from the cap creating U-shaped depressions, and a large opening 260 at the bottom of the cylinder 208 that communicates with outer chamber 204. The device rotates from an inactive position to an activated position, at which point the user may compress the chambers and mix the components.

Haber fails to disclose a freeze-dried medicine in the smaller container. It would have been obvious to one of ordinary skill in the art at the time of invention to use a freeze-dried medicine in the inner container, since it has been held to be within the general skill of a worker in the art to select a known material, such as a freeze-dried

rather than liquid medication, on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

5. Claims 4-5, 8-9, 11, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,352,196 to Haber et al in view of US 6,019,752 to Sunago et al.

In the specification and figures, Haber discloses the invention substantially as claimed by applicant. Haber fails to disclose the particular arrangement of the anchoring member of the interior container. Sunago discloses that the fitting piece or protruding member is molded into the drug storing chamber such that protrusions extend into indentations of the drug storing chamber (see column 4, lines 34-36). It would have been obvious to one of ordinary skill in the art to substitute longitudinal grooves or an indentation in the bottom of the small container as disclosed by Sunago for the sealing ridges of the sealing element of the Haber device, since applicant has not disclosed that the particular arrangement solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the annular ridges of the Haber device to anchor the protruding piece to the medicine chamber.

With regard to applicant's claims drawn to the rigidity of the containers and composition of the rubber plug, it has been held to be within the general skill of a worker in the art to select a known material, such as a rigid plastic, on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to applicant's claims drawn to the integral construction of the pieces, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the pieces as an integral unit, since it has been held that

forming in one piece an article that has formerly been formed in separate pieces and put together involves only routine skill in the art. See MPEP § 2144.04.

Response to Arguments

6. Applicant's arguments filed 19 November 2005 have been fully considered but they are not persuasive.
7. Applicant argues that the Sunago '752 patent does not render the instant application unpatentable, since it lacks the inner medicine chamber. See rejection above referring to claim 5 of the Sunago patent.
8. Applicant argues that the piston 228 of the Haber device is not removed in the operation of the Haber device. Examiner never alleged that such a removal was necessary. The reference to the piston was made to draw an inference of equivalence between applicant's open mouth container 7 and Haber's open mouth container 208. Haber's inner cylinder is just as much of an open mouth container as that illustrated by applicant, regardless of the mode of operation of the Haber device. Applicant illustrates his open mouth container 7 capped by piston 20. Therefore, Haber's open mouth container 208 capped by piston 228 is an equivalent structure to that claimed by applicant.
9. Applicant further argues that the grooves of the Sunago device would render the Haber device inoperable. However, the grooves of the Sunago device exist only to provide a gripping surface the fitting or protruding member such that the member may stabilize one chamber within another. Haber discloses similar such circumferential

grooves, but located on the outside of plug 212, which is attached to inner cylinder 208. The grooves of both device serve to provide a gripping surface for the protruding or fitting member, both of which stabilize the inner container with relation to an outer container. Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

10. Applicant's arguments with respect to claim 10 have been fully considered and are persuasive. The rejection of claim 10 has been withdrawn.

Allowable Subject Matter

11. Claim 10 is allowed.

12. The following is an examiner's statement of reasons for allowance: The prior art fails to disclose or suggest the invention claimed by applicant. In particular, the prior art fails to disclose or suggest the method of storing a medicine in the container system claimed by applicant, comprising the steps of placing the claimed containers in fluid communication with rotational motion, filling the container system, freeze-drying the solution, and storing the medicine, along with the other steps and limitations of the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

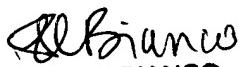
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak
Patent Examiner
Art Unit 3761
23 February 2006


PATRICIA BIANCO
PRIMARY EXAMINER
3/21/06